

Amendments to the Claims:

This listing of the claims will replace all prior versions, and listings, of claims in the present application:

Listing of the Claims:

Claim 1 (currently amended): A pharmaceutical composition in a form of an orally deliverable, sustained release tablet comprising a water-soluble salt of pramipexole, dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN cm² at a solid fraction representative of the tablet as measured using a compact consisting only of said starch, further wherein said tablet provides sustained release as compared with an immediate release pramipexole formulation.

Claim 2 (original): The composition of claim 1 wherein the starch has a tensile strength of at least about 0.175 kN cm².

Claim 3 (original): The composition of claim 1 wherein the starch has a tensile strength of at least about 0.2 kN cm².

Claim 4 (original): The composition of claim 1 wherein the starch is a pregelatinized starch.

Claim 5 (original): The composition of claim 1 wherein the starch is present in an amount of about 25% to about 75% by weight.

Claim 6 (original): The composition of claim 1 wherein the starch is present in an amount of about 40% to about 70% by weight.

Claim 7 (original): The composition of claim 1 wherein the starch is present in an amount of about 45% to about 65% by weight.

Claim 8 (original): The composition of claim 1 wherein the hydrophilic polymer is selected from the group consisting of methylcellulose, hydroxypropylmethylcellulose, carmellose sodium and carbomer.

Claim 9 (original): The composition of claim 1 wherein the hydrophilic polymer is hydroxypropylmethylcellulose.

Claim 10 (original): The composition of claim 1 wherein the hydrophilic polymer is present in an amount of about 20% to about 70% by weight.

Claim 11 (original): The composition of claim 1 wherein the hydrophilic polymer is present in an amount of about 30% to about 60% by weight.

Claim 12 (original): The composition of claim 1 wherein the hydrophilic polymer is present in an amount of about 35% to about 50% by weight.

Claim 13 (original): The composition of claim 1 wherein the salt has solubility not less than about 50 mg/ml.

Claim 14 (original): The composition of claim 1 wherein the salt has solubility not less than about 100 mg/ml.

Claim 15 (original): The composition of claim 1 wherein the salt is pramipexole dihydrochloride.

Claim 16 (original): The composition of claim 1 that comprises about 0. 1 to about 10 mg pramipexole per tablet, expressed as pramipexole dihydrochloride monohydrate equivalent.

Claim 17 (original): The composition of claim 1 that comprises about 0. 2 to about 6 mg pramipexole per tablet, expressed as pramipexole dihydrochloride monohydrate equivalent.

Claim 18 (original): The composition of claim 1 that comprises about 0. 3 to about 5 mg pramipexole per tablet, expressed as pramipexole dihydrochloride monohydrate equivalent.

Claim 19 (original): The composition of claim 1, further comprising a coating on the tablet.

Claim 20 (original): The composition of claim 19 wherein said coating is a release-controlling layer.

Claim 21 (original): The composition of claim 20 wherein said release controlling layer constitutes about 1% to about 15% by weight of the tablet.

Claim 22 (original): The composition of claim 19 wherein said coating is a nonfunctional coating.

Claim 23 (currently amended): A pharmaceutical composition in a form of an orally deliverable, sustained-release tablet having a core comprising pramipexole dihydrochloride monohydrate in an amount of about 0.375, 0.75, 1.5, 3 or 4.5 mg, dispersed in a matrix comprising (a) hydroxypropylmethylcellulose in an amount of about 35% to about 50% by weight of the tablet and (b) a pregelatinized starch having a tensile strength of at least about 0.15 kN cm⁻² at a solid fraction of 0.8 as measured using a compact consisting only of said starch, in an amount of about 45% to about 65% by weight of the tablet; said core being substantially enclosed in a coating that constitutes about 2% to about 7% of the weight of the tablet, said coating comprising an ethylcellulose-based hydrophobic or water-insoluble component and an HPMC-based pore-forming component in an amount of about 10% to about 40% by weight of the ethylcellulose-based component, further wherein said tablet provides sustained release as compared with an immediate release pramipexole formulation.

Claim 24 (currently amended): A method of treatment of a subject having a condition or disorder for which a dopamine D₂ receptor agonist is indicated, the method comprising orally administering not more than once daily to the subject the pharmaceutical composition of claim 1 any of the preceding claims.

Claim 25 (currently amended): The method of claim 24 wherein said the composition is

administered not more than once daily has a core comprising pramipexole dihydrochloride monohydrate in an amount of about 0.375, 0.75, 1.5, 3 or 4.5 mg, dispersed in a matrix comprising (a) hydroxypropylmethylcellulose in an amount of about 35% to about 50% by weight of the tablet and (b) a pregelatinized starch having a tensile strength of at least about 0.15 kN cm² at a solid fraction of 0.8 as measured using a compact consisting only of said starch, in an amount of about 45% to about 65% by weight of the tablet; said core being substantially enclosed in a coating that constitutes about 2% to about 7% of the weight of the tablet, said coating comprising an ethylcellulose-based hydrophobic or water-insoluble component and an HPMC-based pore-forming component in an amount of about 10% to about 40% by weight of the ethylcellulose-based component.

Claim 26 (original): The method of claim 24 wherein the condition or disorder is Parkinson's disease or a complication associated therewith.